K002582

Pilling Weck Surgical

Surgical Innovation Since 1814

NOV - 3 2000

510(K) Summary

1. Submitter Name, Address, and Date of Submission.

Elizabeth Lazaro
Pilling Surgical
420 Delaware Drive
Fort Washington, PA 19034
Telephone Number (800) 523-6507
Fax Number (215) 646-5622

Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Electrosurgical Suction Tube

Common Name: Suction Tube Coagulator

Proprietary Name: Pilling e-Frazier Bipolar Suction Tube

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Pilling e-Frazier Bipolar Suction Coagulator

4. Description of the Device.
The Pilling e-Frazier is a sterile, disposable, surgical device provided complete with bipolar cables. When connected to an electrosurgical generator and suction port, the Pilling e-Frazier provides the ability to coagulate tissue at the distal tip and suction blood and the surgical debris from the site.

5. Intended Use of the Device.
The Pilling e-Frazier Suction tube is intended to coagulate and suction blood and surgical debris, to perform spot coagulation of bleeding vessels.

6. Summary of Technological Characteristics.
The technological characteristics are the same as, or equivalent to, predicate devices Surgical Laser Technologies (K984018).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2000

Ms. Elizabeth Lazaro
Pilling Surgical
420 Delaware Drive
Fort Washington, Pennsylvania 19034

Re: K002582
Trade Name: Pilling e-Frazier Bipolar Suction Coagulator Tube
Regulatory Class: II
Product Code: GEI
Dated: August 14, 2000
Received: August 18, 2000

Dear Ms. Lazaro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K002582

Device Name: Pilling e-Frazier Bipolar Suction Coagulator Tube

Indications for Use:

To coagulate and suction blood and surgical debris; to perform spot coagulation of bleeding vessels.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002582

Prescription Use ✓ **or Over-The-Counter Use** _____

(Per 21 CFR 801.1 09)